K022009

IMPLANT INNOVATIONS, INC.
A BIOMET COMPANY

DEC 3 0 2002

Summary of Safety & Effectiveness

COMPANY:

Implant Innovations, Inc.
4555 Riverside Drive
Palm Beach Gardens, FL 33410

CONTACT:

Jeannette G. Dailey, RAC
Regulatory Affairs Manager
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DATE PREPARED: June 18, 2002

NAME OF THE DEVICE: *3i* Dental Implant Systems

CLASSIFICATION: DZE Class III

COMMON NAME: Endosseous Dental Implants

PREDICATE DEVICES: OSSEOTITE NT™ Implant System

- K014265 for clearance of the system on May 16, 2002

OSSEOTITE® Dental Implants cleared for marketing via the following premarket notifications:

- K935544 for an acid-etched process to create the OSSEOTITE brand surface cleared on March 13, 1995,
- K980549 for a performance claim cleared on April 28, 1998,
- K983347 for a performance claim cleared on January 1, 1999, and
- K013570 for Instructions for Use changes cleared on December 18, 2001.

3i Dental Implant Systems

- K874590 for clearance of the system on May 11, 1988.

DEVICE DESCRIPTION:

Implant Innovation's dental implant systems are available in a wide range of diameters and lengths. *3i* implants include screw-form (i.e., threaded) or cylinder; are manufactured from titanium; and are coated or non-coated. The OSSEOTITE® brand implants have a special dual acid-etched treatment process to increase surface roughness.

INDICATIONS FOR USE:

The Implant Innovation's dental implant systems are indicated for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment to restore a patient's chewing function.

CONTRAINDICATIONS:

Placement of *3i* dental implants may be precluded by patient conditions that are contraindications for surgery.

3i implants should not be placed on patients where the remaining jaw bone is too diminished to provide adequate implant stability.

WARNINGS

Excessive bone loss or breakage of implant may occur when an implant is loaded beyond its functional capability.

Physiological and anatomic conditions may negatively affect the performance of dental implants. This should be taken into consideration when placing dental implants in patients with the following*:

- Poor quality bone
- Poor oral hygiene
- Medical conditions such as blood disorders or uncontrolled hormonal conditions

* Clinical data have demonstrated enhanced performance of Osseotite® implants as compared to other *3i* implants in patients with poor quality bone.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 3 0 2002

Ms. Jeannette G. Dailey
Regulatory Affairs Manager
Implant Innovations, Incorporated
4555 Riverside Drive
Palm Beach Gardens, Florida 33410

Re: K022009
Trade/Device Name: 3i Dental Implant System
Regulation Number: 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: III
Product Code: DZE
Dated: December 13, 2002
Received: December 16, 2002

Dear Ms. Dailey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K022009

510(k) Number (if known): K022009

Device Name: *3i* Dental Implant System

Indications for Use:

3i Dental Implant Systems are indicated for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment to restore a patient's chewing function.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert S Betz DDS for Dr. Susan Runner
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K022009

Prescription Use:_____ OR Over the Counter Use:_____
(Per 21 CFR 801.109)